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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WORTMAN, DONNA C

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 08/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,501

Applicant(s)

PAUL ET AL.

Examiner

Donna C. Wortman, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/18/03; 5/19/03; 5/27/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-29 and 32-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30,31,39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20,23. 6) ☐ Other: _____

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 May 2003 has been entered.

The previously unentered amendment after final filed 18 April 2003 has been entered as requested. By its entry, claim 30 was amended and claims 39 and 40 were added. Claims 1-29 and 32-38 remain pending but withdrawn from consideration as drawn to non-elected invention. Claims 30, 31, 39 and 40 are under examination.

Claims 30 and 31 are drawn to a diagnostic kit for assaying PRRSV comprising two primers, each 10-50 nucleotides in length, that hybridize to a genomic polynucleic acid from an Iowa strain of the virus but do not hybridize to polynucleic acid from Lelystad virus at a specified temperature range. Claims 39 and 40 are drawn to a diagnostic kit for assaying PRRSV comprising two primers, each 10-50 nucleotides in length, that hybridize to genomic polynucleic acid from an Iowa strain of the virus and also hybridize to polynucleic acid from Lelystad virus at a specified temperature range.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30, 31, 39 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. No support could be located in the specification as filed for pairs of primers that hybridize with genomic polynucleic acids from deposited Iowa virus strains but not with Lelystad virus, and/or for additional pairs of primers that hybridize with both Applicant's Iowa virus strains and Lelystad virus.

Although Applicant has pointed to the specification at page 28, lines 16-21; page 29, line 21-page 30, line 3; page 40, line 15-page 41, line 1; page 41, lines 8-16, and has asserted that support for the subject matter as now claimed can be found at these locations, it is not agreed that these portions of the specification when taken in context convey that Applicant had possession of pairs of primers that hybridize with genomic polynucleic acids from deposited Iowa virus strains but not with Lelystad virus, and/or additional pairs of primers that hybridize equally well with Applicant's Iowa virus strains and Lelystad virus. At best, the specification at pages 40 and 41 disclose that primers can be designed, but no primers are actually described. Applicant has argued that "such primers could be easily identified given the sequence comparisons of Figures 8-11, 17 and 21." This argument has not been found persuasive. Figures 8-11 present a comparison of the nucleotide sequences of various genome regions of VR 2385 and Lelystad virus, but do not indicate any primers. Figure 17 presents a comparison of ORFs 6 and 7 of six U.S. PRRSV isolates with corresponding regions of Lelystad virus,

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and Figure 21 compares nucleotide sequences of ORFs 2, 3, and 4 of VR 2385 with corresponding regions of Lelystad virus, ^{but} there is no disclosure or identification of any primers. Applicant's assertion that "primers could be easily identified" is not persuasive because the present issue is the lack of written description of the invention as claimed rather than the lack of enabling disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
August 7, 2003